

GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201 USA

K012389

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

<u>Identification of Submitter</u>: Larry A. Kroger, Ph.D.

Senior Regulatory Programs Manager

GE Medical Systems Tel. (262) 544-3894

Summary prepared: 25 June 2001

Identification of Product:

Revolution XR/d Digital Radiographic Imaging System

Classification Name:

Stationary X-ray System GE Medical Systems

Manufacturer: GE Medical Systems 3000 N. Grandview Blvd.

Waukesha, WI 53188

Device Description:

The Revolution XR/d Digital Radiographic Imaging System is designed to perform radiographic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a DICOM network for applications such as printing, viewing, and storage. The Revolution XR/d Digital Radiographic Imaging System consists of an elevating radiographic table with integrated digital detector, x-ray tube, x-ray tube hanger, collimator, system controller, generator, and tilting radiographic wall stand with integrated digital detector. The configuration can consist of digital table and digital wall stand, digital table only, or

digital wall stand only.

Indications for Use:

The Revolution XR/d Digital Radiographic Imaging System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This

device is not intended for mammographic applications.

Comparison with:

The Revolution XR/d Digital Radiographic Imaging System is an enhanced version of and substantially equivalent to the

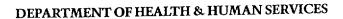
Revolution XR/D Digital Radiographic Imaging System, originally cleared in K992066.

Conformance:

The Revolution XR/d Digital Radiographic Imaging System will conform to applicable sections of 21CFR 1020.30, 1020.31, and 1020.32. The system will also conform to UL 2601-1, IEC 601-1, IEC 601-1-2, and IEC 601-1-3.

Conclusions:

In the opinion of GE Medical Systems, the Revolution XR/d Digital Radiographic Imaging System is substantially equivalent to the presently marketed Revolution XR/D Digital Radiographic Imaging System (K992066). The Revolution XR/d Digital Radiographic Imaging System does not include any new indications for use, nor does use of this device result in any new potential hazards.





AUG 1 0 2001

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

GE Medical Systems, Inc. % Mr. Reiner Krumme Manager, Medical Division TUV Rheinland of North America 12 Commerce Road NEWTON CT 06470 Re: K012389

Revolution XR/D Digital Radiographic Imaging System

(Radiographic x-ray system with SSXI)

Dated: July 23, 2001 Received: July 27, 2001 Regulatory Class: II

21 CFR 892.1630/Procode: 90 MQB 21 CFR 892.1680/Procode: 90 KPR

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for <u>in vitro</u> diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Mancy Clarogatin Nancy C. Brogdon

Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

STATEMENT OF INTENDED USE

510(k) Number (if known): <u>K 012389</u>
Device Name: Revolution XR/d Digital Radiographic X-ray System
Indications for Use
The Revolution XR/d Digital Radiographic X-ray System is indicated for use in generating radiographic images of human anatomy. It is intended for use in replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use OR Over-The-Counter Use (Per 21 CFR 801-109)
(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number